

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A.,
INC.,

Plaintiff,

vs.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

C.A. No. 13-cv-1729-SLR

DECLARATION OF CHAD S. BOOMERSHINE, M.D., Ph.D.

I, Chad S. Boomershine, M.D., Ph.D., declare as follows:

1. I am a Board Certified physician in internal medicine and rheumatology. I received my M.D. and Ph.D. from the Ohio State University College of Medicine and Public Health in 2002. Following medical school, I completed a residency in internal medicine in 2004 and clinical fellowship in rheumatology in 2005 both at Vanderbilt University.

2. I currently am Medical Director of Boomershine Wellness Centers in Nashville, Tennessee. I also am an Assistant Clinical Professor of Medicine at Vanderbilt University.

3. As a Board Certified Rheumatologist, I specialize in the care of patients with rheumatic diseases including gout, arthritis, fibromyalgia, chronic fatigue syndrome as well as the rare disease Familial Mediterranean Fever ("FMF").

4. I understand that recent estimates from the Center for Disease Control and American College of Rheumatology indicate that more than 8.3 million people in the United States suffer from gout. Gout is the most common form of inflammatory arthritis. In contrast, by comparison the number of patients in the United States suffering from FMF is very small. FMF is classified as a rare disease because it affects less than 200,000 people in the United States.

5. Over my twelve year career, I have treated hundreds of patients suffering from gout. In comparison, in that same time period, I have only treated a single patient suffering from FMF. In my experience, my limited exposure to FMF patients is not uncommon for a rheumatologist given the lack of prevalence of the disease in the United States.

6. I routinely prescribe Colcrys®, an orally administered pharmaceutical product containing the active ingredient colchicine, for patients to treat and prevent gout flares. Over the past three years, I have frequently prescribed Colcrys® for the treatment and prevention of gout flares. In comparison, in that same time period, I have not once prescribed Colcrys® to treat FMF.

7. I understand that in 2009 the United States Food and Drug Administration (“FDA”) approved Colcrys® for the treatment and prevention of gout flares. I am also aware that Colcrys® remains the only FDA approved oral colchicine product available for physicians to prescribe for the prevention and treatment of gout flares.

8. As a practicing physician, I am aware that the FDA does not regulate or mandate the choice of medications prescribed by a physician. Rather, a physician’s prescribing decision is generally based on knowledge, experience, training, review of the medical literature and review of the Physician’s Desk Reference or package insert for the brand drug, which is the first version of the drug that comes to market. By the time a generic version of a branded drug becomes available, I and other physicians typically have had years of experience prescribing the brand drug.

9. My knowledge of approved indications also comes from the indications included in the brand name drug label. I have never relied on any information from a generic drug company when making prescribing decisions. I have never reviewed a label from a generic drug maker when deciding whether to prescribe a drug, the dose or dosing frequency of a drug, or the indication for which to prescribe a drug. Moreover, I have never received and to the best of my recollection have never seen a generic drug label, including its approved indications. Based on

my interactions with other physicians I believe my experience as described in this paragraph to be similar to that of most physicians.

10. Prior to 2009, unapproved colchicine was prescribed in the United States for the treatment and prevention of gout flares, and the only way to prescribe the drug before that time was to use the term “colchicine.” In 2009, Colcrys® was approved by the FDA. Based on my experience reviewing patient histories as well as through interactions with other physicians that use colchicine to treat gout, many physicians have maintained the practice of using the phrase “colchicine” (instead of Colcrys®) when writing prescriptions for patients suffering from gout flares.

11. In my experience practicing over the past twelve years and in discussing the use of generic products with my colleagues, attending seminars and reading literature, most prescribing physicians assume that when a generic drug is made available it can be prescribed for any approved indication associated with the brand name drug. Colcrys® is approved for the prevention and treatment of gout flares as well as treatment of FMF. Accordingly, if a generic version of Colcrys® is made available for treatment of FMF, I would expect that practicing physicians would also start prescribing “colchicine” for gout patients.

12. Physicians make the decision to prescribe a particular drug. They generally are not involved in the decision of how to fill the prescription. In particular, physicians do not generally control whether a pharmacist fills a prescription for a given drug with a brand drug product or with a generic product. Unless physicians specify on the prescription that only the brand drug should be dispensed (“Dispense as Written” or “DAW” or “Brand Only”) pharmacists will generally fill that prescription with a generic version due to cost concerns. Further, I am aware that many states have substitution laws that require a pharmacist to distribute generic versions of drugs (if available) instead of the brand named drug, unless specifically prohibited by the prescribing physician. One effect of these prescribing practices is that pharmacists will tend to fill a prescription for colchicine with a generic version of Colcrys®, if one is available.

I declare that the foregoing statements are true and accurate, and that this declaration is made under penalty of perjury under the laws of the State of Tennessee and the United States.

A handwritten signature in black ink, appearing to read 'Chad S. Boomershine', is written over a horizontal line.

Chad S. Boomershine, M.D., Ph.D.

Dated April 30, 2014